

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of the Inspector General of the Department of Health and Human Services, the United States Department of Veterans Affairs, the United States Department of Defense, and Dr. Jeffrey R. Carlson (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Dr. Jeffrey R. Carlson (“Dr. Carlson”) is an orthopedic surgeon practicing in Newport News, Virginia.

B. SpineFrontier, Inc. (“SpineFrontier”) is a corporation with an office in Malden, Massachusetts. At all times relevant to this agreement, Dr. Kingsley R. Chin owned 98.6% of SpineFrontier through KICVentures, LLC and other affiliated companies that he wholly owned. At all relevant times, SpineFrontier developed, manufactured, distributed, marketed, and sold medical devices used during spine surgeries.

C. Impartial Medical Experts, LLC (“IME”) is a Florida-based legal entity that Dr. Kingsley R. Chin wholly owned through KICVentures, LLC and other affiliated companies that he wholly owned. At all relevant times, IME’s “Business Administrator” and sole employee was Vanessa J. Dudley, Chin’s wife.

D. The United States contends that Dr. Carlson submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”), the Veterans Health Administration, 38 U.S.C. Chapter 17 (“VA”), and TRICARE, 32 C.F.R. § 199.17 (collectively, “Federal Health Care Programs”).

E. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (“AKS”), prohibits the payment or receipt of remuneration to induce or reward the purchase of an item or service for which payment is made in whole or in part under Federal Health Care Programs. A claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the False Claims Act, 31 U.S.C. § 3730 *et seq.*

F. The United States contends that it has certain civil claims against Dr. Carlson for submitting or causing the submission of false claims to that resulted from violations of the AKS, in connection with the conduct described in Paragraph G below.

G. Dr. Carlson admits, acknowledges, and accepts his responsibility for the following facts:

1. On or about February 15, 2013, Dr. Carlson entered into a consulting agreement with SpineFrontier ostensibly to provide feedback on the design and usability of SpineFrontier medical devices. Pursuant to the February 15, 2013, consulting agreement, SpineFrontier agreed to pay Dr. Carlson at a rate of \$500 per hour.
2. On or about October 4, 2013, SpineFrontier informed Dr. Carlson that it had “outsourced” its consulting services to IME, and Dr. Carlson signed a new consulting agreement with IME on or about October 29, 2013. Dr. Carlson did not perform consulting services for any company other than SpineFrontier pursuant to the IME agreement. Under the October 29, 2013, consulting agreement, SpineFrontier agreed to pay Dr. Carlson \$500 per hour.
3. Between February 15, 2013, and December 31, 2018, SpineFrontier paid Dr. Carlson directly, and indirectly through IME, a total of \$1,268,511 in consulting fees. During this time, Dr. Carlson utilized SpineFrontier products, including in surgical procedures for which Federal Health Care Programs reimbursed Dr. Carlson.
4. Dr. Carlson knew he could not bill SpineFrontier for verbal feedback he provided during his surgical procedures. Dr. Carlson submitted consulting time to SpineFrontier based on guidelines SpineFrontier communicated to him. Specifically, Dr. Chin instructed Dr. Carlson to bill the time that Dr. Carlson spent thinking about the evaluation and development of SpineFrontier products. Dr. Carlson estimated his consulting hours based, in part, on the number of surgeries he performed with SpineFrontier products in a given month. Dr. Carlson cannot document all of the consulting hours he submitted to SpineFrontier. SpineFrontier paid Dr. Carlson, in

part, for verbal feedback he provided during surgery, despite the IME agreement's stated exclusion of such time.

5. SpineFrontier provided Dr. Carlson and his surgical staff with free lunch on almost every day that Dr. Carlson performed surgery with SpineFrontier's products. Dr. Carlson never reimbursed SpineFrontier for the cost of these lunches. The cost of SpineFrontier's free lunches to Dr. Carlson and his staff was multiple hundreds of dollars per year.
6. SpineFrontier did not communicate to Dr. Carlson that his purported consulting work was unsatisfactory, even when SpineFrontier paid Dr. Carlson for product evaluations with minimal or no substantive content.

The conduct described in this Paragraph G shall hereinafter be referred to as the "Covered Conduct."

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Dr. Carlson shall pay to the United States \$1,750,000, plus interest at a rate of 1.625% per annum from February 6, 2020, through the day before full payment (the "Settlement Amount"), by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts. Of the Settlement Amount, Dr. Carlson shall pay to the United States \$1,600,000, plus accrued interest, no later than 30 days after the Effective Date of this Agreement. Dr. Carlson shall pay to the United States the balance of the Settlement Amount, plus accrued interest on that balance, no later than 180 days after the Effective Date of this Agreement. Of the Settlement Amount, \$875,000 is restitution to the United States.

2. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, and conditioned upon Dr. Carlson's full payment of the Settlement Amount, the United States releases Dr. Carlson from any civil or administrative monetary claim the United States has for

the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12; or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. Notwithstanding the release given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals other than Dr. Carlson;
- g. Any liability for failure to deliver goods or services due; and
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Dr. Carlson waives and shall not assert any defenses Dr. Carlson may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment

of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

5. Dr. Carlson fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Dr. Carlson has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE, the VA, or any state payer, related to the Covered Conduct; and Dr. Carlson agrees not to resubmit to any Medicare contractor, TRICARE, the VA, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

7. Dr. Carlson agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Dr. Carlson, his employees, and his agents in connection with:

(1) the matters covered by this Agreement;

- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Dr. Carlson's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Dr. Carlson makes to the United States pursuant to this Agreement

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Dr. Carlson, and Dr. Carlson shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Dr. Carlson or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment:
Dr. Carlson further agrees that within 90 days of the Effective Date of this Agreement he shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program,

including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Dr. Carlson or any of its employees or agents, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Dr. Carlson agrees that the United States, at a minimum, shall be entitled to recoup from Dr. Carlson any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Dr. Carlson on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Dr. Carlson's cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Dr. Carlson's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

8. Dr. Carlson agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement.

9. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 10 (waiver for beneficiaries paragraph), below.

10. Dr. Carlson agrees that he waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents,

sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

11. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

13. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

14. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

15. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

16. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

17. This Agreement is binding on Dr. Carlson's successors, transferees, heirs, and assigns.

18. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

19. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 4/24/2020 BY: 

ABRAHAM R. GEORGE

DAVID J. DERUSHA

STEVEN T. SHAROBEM

Assistant United States Attorneys

United States Attorney's Office

District of Massachusetts

DATED: _____

BY: _____

LISA M. RE

Assistant Inspector General for Legal Affairs

Office of Counsel to the Inspector General

Office of Inspector General

United States Department of Health and Human Services

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

ABRAHAM R. GEORGE

DAVID J. DERUSHA

STEVEN T. SHAROBEM

Assistant United States Attorneys

United States Attorney's Office

District of Massachusetts

DATED: 04/24/2020

BY: Lisa M. Re

LISA M. RE

Assistant Inspector General for Legal Affairs

Office of Counsel to the Inspector General

Office of Inspector General

United States Department of Health and Human Services

DR. JEFFREY CARLSON - DEFENDANT

DATED: 9/23/20

BY: 

DR. JEFFREY R. CARLSON

DATED: 4.23.20

BY: 

JOHN D. ADAMS

BRANDON M. SANTOS

McGuire Woods LLP

Counsel for Dr. Jeffrey R. Carlson